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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/645,335	08/21/2003	Masakazu Takeuchi	2003946-0055 (Rabconnecti	7601

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EXAMINER
ROOKE, AGNES BEATA

ART UNIT	PAPER NUMBER
1653	

Patent Department
Attn Charles E Lyon
Choate Hall & Stewart
Exchange Place
Boston, MA 02109

DATE MAILED: 04/20/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/645,335	TAKEUCHI ET AL.	
	Examiner	Art Unit	
	Agnes B Rooke	1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-31 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-31 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1 and 2, drawn to a protein of SEQ ID NO:2, classified in class 530, subclass 350.

II. Claims 3-8, and 25-27, drawn to a DNA of SEQ ID NO:1; a vector; and host cells; classified in class 435, subclass 69.1.

III. Claim 9, drawn to a method of producing a protein, classified in class 514, subclass 12.

IV. Claims 11-14, and 30, drawn to a method of analyzing DNA, classified in class 435, subclass 6.

V. Claim 15, drawn to a method of amplifying mRNA, classified in class 435, subclass 6.

VI. Claim 16, drawn to antisense DNA, classified in class 435, subclass 6.

VII. Claims17 and 18, drawn to a ribozyme, and double stranded RNA, classified in class 435, subclass 6.

VIII. Claim 19, drawn to an antibody, classified in class 530, subclass 387.1.

IX. Claim 20-22, drawn to a method of immunohistologically analyzing a protein, classified in class 435, subclass 7.1.

X. Claim 23, drawn to a method of screening for a material that binds rabconnectin-3, classified in class 514, subclass 12.

XI. Claim 24, drawn to a method of screening for a material that binds to Rab 3GDP/GTP.

XII. Claim 28, drawn to a method of producing a protein that binds to rabconnectin-3 and a GDP/GTP, classified in class514, subclass 12.

XIII. Claim 29, drawn to a method of analyzing DNA, classified in class 435, subclass 6.

XIV. Claim 31, drawn to a method of amplifying mRNA, classified in class 435, subclass 6.

The inventions are distinct, each from the other because of the following reasons:

The nucleic acids of Invention II are related to the proteins of Invention I by virtue of encoding the same. Although the DNA molecule and protein are related, since the DNA encodes the specifically claimed protein, they are distinct inventions because the protein product can be made by another and materially different process, such as synthetic peptide synthesis or purification from the natural source.

The nucleic acid of Invention II and the antibody of Invention VIII are related by virtue of the protein that is encoded by the nucleic acid and necessary for the production of the antibody. However, the nucleic acid itself is not necessary for an antibody production and both are different compounds having different compositions and functions. Therefore, the inventions are distinct.

The protein of Invention I and the antibody of Invention VIII are patently distinct for the following reasons: protein and antibody are structurally different molecules; and any relationship between antibody and a protein is dependent upon correlation between the scope of the proteins that the antibody binds and the scope of the antibodies that would be generated upon immunization with the protein. Therefore, the inventions are distinct.

Inventions III, IX, X, XI, XII (using a protein), Inventions IV, V, VI, XIII, XIV (using DNA) are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the inventions use different products, have different starting and ending points and have different modes of operations.

Invention I and Inventions III, IX, X, XI, XII are related as process of making and process of using the product. The use as claimed cannot be practiced with a materially different product. Since the product is not allowable, restriction is proper between said method of making and method of using. The product claim will be examined along with the elected invention (MPEP § 806.05(i)). In the instant case, the protein can be used in different methods as demonstrated in Inventions III, IX, X, XI, XII. Therefore, the inventions are distinct.

Invention II and Inventions IV/V/VI/XIII/XIV are related as process of making and process of using the product. The use as claimed cannot be practiced with a materially different product. Since the product is not allowable, restriction is proper between said method of making and method of using. The product claim will be examined along with the elected invention (MPEP § 806.05(i)). In the instant case, the composition of Invention II can be used in different methods as disclosed in Inventions IV/V/VI/XIII/XIV. Therefore, the inventions are distinct.

Inventions I/II/VI/VII/VIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, a protein, DNA, a ribozyme, an antibody are different and distinct compositions with different chemical structure and different physicochemical characteristics.

Inventions I and IV/V/XIII/XIV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the protein of invention cannot be used in Inventions IV/V/XIII/XIV.

Inventions II and III/IX/X/XI/XII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the DNA of invention II cannot be used in inventions III/IX/X/XI/XII.

Inventions VII and III/IV/V/X/IX/XI/XII/XIII/XIV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the ribozyme of invention VII cannot be used in inventions III/IV/V/X/IX/XI/XII/XIII/XIV.

Inventions VIII and III/IV/V/X/IX/XI/XII/XIII/XIV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the antibody of invention VIII cannot be used in inventions III/IV/V/X/IX/XI/XII/XIII/XIV.

Because the inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for the examination purposes as indicated is proper.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain

dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Applicant is advised that the reply to this requirement to be complete must include an election of the Invention to be examined even though the requirement be traversed (37 CFR 1.143).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Agnes Rooke whose telephone number is 571-272-2055. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached on 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information about the PAIR system, see http://pair-direct.uspto.gov, or call 866-217-9197.

AR

JON WEBER
SUPERVISORY PATENT EXAMINER